

**Notice of Allowability**

Application No.

10/823,964

Applicant(s)

BAM ET AL.

Examiner

Cherie M. Woodward

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to After-Final Amendment filed 7/3/2007.
2. ☒ The allowed claim(s) is/are 1,3-6,9-20,26-35,37,38,42,43,45 and 47.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 7/18/2007.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

  
GARY B. NICKOL, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

## EXAMINER'S AMENDMENT

An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Applicant's representative Elizabeth Hecht on 18 July 2007 at 1:45pm. Authorization was given to cancel claims 2, 23, 24, and 25, and to amend the claim language of claims 1, 6, and 9-11. Claims 3-5, 26-28, 30-35, and 43 are rejoined by the Examiner (see Examiner's Comments).

### In the claims:

**Cancel withdrawn claims 2, 22, 23, and 24.**

**In claim 1, line 3, replace the phrase "...one to five amino..." with the phrase "...three to five amino..."**

**In claim 6, line 1, replace the phrase "The human IL-18" with the phrase "A human IL-18"**

**Claim 9 is amended to recite:** "A composition comprising a polypeptide conjugated to a water-soluble polymer, wherein the polypeptide is the human IL-18 substitution mutant selected from the group consisting of SEQ ID NO: 5, 6, 7, 8, 9, and 10.

**Claim 10 is amended to recite:** "The composition as recited in claim 9, wherein the polypeptide comprises SEQ ID NO: 8 and wherein the conjugation between the polypeptide and the polymer is covalent."

**Claim 11 is amended to recite:** "The composition as recited in claim 8, wherein the polypeptide comprises SEQ ID NO: 8 and wherein the water-soluble polymer is a member chosen from the group of: polyethylene glycol homopolymers, polyethylene glycol copolymers, polypropylene glycol homopolymers, poly(N-vinylpyrrolidone), poly(vinyl alcohol), poly(ethylene glycol-co-propylene glycol), poly(N-2-(hydroxypropyl)methacrylamide), poly(sialic acid), poly(N-acryloyl morpholine), and

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dextran.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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## EXAMINER'S COMMENTS

1. Applicant's Amendments to the claims and the specification, filed 3 July 2007, are acknowledged and entered.

### *Interview Summary*

2. A telephonic interview was held with Applicant's Representative, Elizabeth Hecht, on 18 July 2007 at 1:45pm. The Interview Summary is attached.

### *Rejoinder*

3. Claims 3-5, 26-28, 30-35, and 43 are rejoined, as being drawn to species that are dependent on allowable, generic claim 1. Pursuant to the procedures set forth in MPEP § 821.04(b), claims 3-5, 26-28, 30-35, and 43, drawn to human IL-18 substitution mutants comprising at least three of the amino acid substitutions recited in generic claim 1, including SEQ ID NOs: 5, 6, 7, 8, and 10, previously withdrawn from consideration as a result of a restriction and species requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claims 2 and 25, directed to human IL-18 substitution mutants comprising only one amino acid substitution (SEQ ID NO: 4), do not fall within the claimed limitations of generic claim 1 and have NOT been rejoined.

Claims 23 and 24, drawn to a method of treating cancer, remain restricted and withdrawn from consideration, pursuant to the restriction requirement of 1 February 2006.

It is noted that Applicant's representative provided authorization to cancel claims 2, 23, 24, and 25, during the telephonic Interview of 18 July 2007.

### *Claim Objections/Rejections – Withdrawn*

4. The rejections/objections drawn to claims 22, 36, 40, 41, 44, and 46 are withdrawn as moot, in light of Applicant's cancellation of the claims in the amendment filed 3 July 2007.
5. The objection to the specification are withdrawn in light of Applicant's amendments, filed 3 July 2007.
6. The objection to claim 6 is objected to as being dependent upon a rejected base claim, is moot in light of Applicant's amendments, filed 3 July 2007.

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7. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al., EP 0845530 A3 (published 3 June 1998) (see especially, SEQ ID NO: 7 and claim 5) (cited in the Office Action of 17 October 2006), is withdrawn in light of Applicant's amendments, filed 3 July 2007, and the Examiner's Amendments, attached hereto.

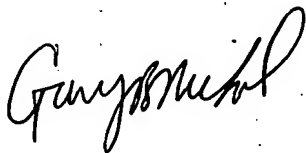
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